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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/649,609	08/28/2003	Nabil El-Tayar	EL-TAYAR3B	5287

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EXAMINER	
SEHARASEYON, JEGATHEESAN	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/649,609	EL-TAYAR ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *5-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I drawn to claims 1-4 in the reply filed on 6/28/06 is acknowledged. Claims 5-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/28/06.

Drawings

2. The drawings filed 8/28/2003 are acknowledged.

Information Disclosure Statement

3. The IDS submitted 8/28/2003 has been considered. The references are found in 09/698133.

Specification

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

5. Applicant is required to update the priority information by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6a. Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method of treatment of viral infections including hepatitis B and C, basal cell carcinoma, brain tumor, skin cancer and multiple sclerosis by administering a polyol-interferon-β conjugate, the specification does not reasonably provide enablement for the method of treating all infections, tumors and autoimmune and inflammatory diseases by administering a polyol-interferon-β conjugate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 1-4 are drawn to the method of treating infections, tumors and autoimmune and inflammatory diseases by administering a polyol-interferon-β conjugate. However, prior art has disclosed treatment of viral infections including

hepatitis B and C, basal cell carcinoma, brain tumor, skin cancer and multiple sclerosis (immune related disease) by administering interferon-β (Johnson et el, page 74; Platz et al. U.S. Patent No. 6, 479, 049, column 5). The specification as filed is insufficient to enable one skilled in the art to practice the claimed invention of treating infections to its full scope without an undue amount of experimentation because infections could be caused by various etiologies. For example, infection could result from bacteria, virus, yeast or parasite. However, the prior art only teaches that viral infections (hepatitis B and C) maybe treated by interferon-β (Platz et al. U.S. Patent No. 6, 479, 049, column 5). Similarly, the specification as filed is insufficient to enable one skilled in the art to practice the claimed invention of treating tumors to its full scope without an undue amount of experimentation because tumors could be caused by various etiologies and present in different tissues. While, the prior art teaches that basal cell carcinoma, brain tumor and skin cancer respond to interferon-β, the art also teaches that hairy cell leukemia, Kaposi's sarcoma, colon tumors, and kidney tumors respond to interferon alpha and gamma (Johnson et el, page 74; Platz et al. U.S. Patent No. 6, 479, 049, column 5).

Prior art also teaches that multiple sclerosis (an inflammatory disease) is treated by interferon-β(Johnson et el, page 74; Platz et al. U.S. Patent No. 6, 479, 049, column 5) yet the scope of the claims encompasses all autoimmune and inflammatory diseases of the subject. Inflammatory pathology is associated with various diseases including transplant tissue rejection (graft-versus-host-disease), psoriasis, periodontitis, arthritis, asthma, multiple sclerosis and others.

The usefulness of the methods for treatment recited in the claims is tied to the usefulness of polyol-interferon-β conjugate in treating viral infections including hepatitis B and C, tumors including basal cell carcinoma, brain tumor, skin cancer, and multiple sclerosis an inflammatory disease. Since, neither the prior art nor the specification teaches that interferon-β is capable of treating of all infections, all tumors and all autoimmune and inflammatory diseases, it is unclear how one skilled in the art in the absence of direction provided by the inventor or the prior art can utilize the teachings of the instant invention to administer an effective amount of interferon to treat diseases disclosed in the instant claims and to the full extent of the scope of the claims.

If one skilled in the art is not guided as to the pathology of the various diseases, then the skilled artisan is also not guided as to how to use methods for the treatment using the interferon-β conjugate polypeptide. Since, there is inadequate guidance as to the nature of the invention, it is merely an invitation to the artisan to use the current invention as a starting point for further experimentation to try to formulate a treatment for various diseases with unrelated etiologies. In addition, because there are no working examples provided describing diseases or models or modes of action for interferon-β, it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention in its full scope.

In addition, there is no guidance provided for the mechanism associated with the various disease pathology recited in the claims. While mechanism is not required, it can allow extrapolation of enablement to non-exemplified embodiments. Since applicant has not provided any working examples to teach the method of treatment of a subject

suffering from infections, tumors and autoimmune and inflammatory diseases by administering an effective amount of polyol-interferon-β conjugate either *in vitro* or *in vivo*, it would require an undue amount of experimentation to one of skill in the art to practice the invention commensurate in scope with the claims to treat all diseases disclosed.

Given the breadth of claims 1-4 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for a method of treatment of a subject suffering from infections, tumors and autoimmune and inflammatory diseases by administering an effective amount of polyol-interferon-β conjugate.

6b. Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The specification discloses human fibroblast interferon (IFN-β). This meets the written description provisions of 35 USC 112, first paragraph. However, the specification does not disclose all possible native sequences contemplated by the Applicant. The claims as written, however, encompass variant sequences of polypeptide interferon-β

which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claim 4. The specification does not provide written description to support the genus encompassed by the instant claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (*See Vas-Cath* at page 1116).

With the exception of human fibroblast interferon (IFN-β), the skilled artisan cannot envision all the detailed chemical structure of the native human interferon-β, regardless of the complexity or simplicity of the method of isolation.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

Therefore, only the human fibroblast interferon (IFN-β) but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of various of native human interferon-β set forth in claim 4.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7a. Claim 4 is rejected as vague and indefinite for reciting the term "same or higher interferon-β activity". It is unclear what interferon-β activity is contemplated because interferon-β has many activities including antiviral activity, antiproliferative and anti-inflammatory activity etc and the specification only discloses increased interferon-β biological activity. Therefore, the metes and bounds are unclear with respect to the interferon-β activity contemplated by the instant invention.

7b. Claim 4 is rejected as vague and indefinite for reciting the term "native human interferon-β". In the absence of the description of all naturally occurring human interferon-β species the metes and bounds are unclear. The specification discloses (see page 1, line 17) possession of a single species, not all naturally-occurring variants etc.

Conclusion

8. No Claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jegatheesan Seharaseyon

Patent Examiner.

JSS
Art Unit 1647,
October 5, 2006